

Title: Catheter and method, in particular for ablation and like such techniques.

The invention relates to a catheter. The invention relates in particular to a catheter for ablation in body cavities such as blood vessels or organs such as a heart.

5 It is known to perform treatments in a human or animal body with the aid of catheters with having an electrically conductive first end. This ablation electrode is typically present on the extremity end of the catheter. Also, elaborations There are known also embodiments with several ablation electrodes one behind the other on the catheter which is inserted into the said cavity mentioned. The patient is then laid on a conductive plate, for instance an earthed grounding plate. Then, through the catheter, an electric current is passed through the catheter, which current flows runs through the body. If the first end is held against or at a very short distance from a wall of the body cavity, this said wall will be heated locally over a relatively small area; as a result of the electrical resistance of the wall. Consequently, in this area, ablation occurs in said area. As a result thereof, part of the tissue of this said wall dies.

10 With this treatment, for instance heart rhythm disturbances cardiac arrhythmias can be treated and be prevented for in the future.

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During this known treatment, known per se, it is of importance that the temperature of, in particular, the said first part end of the catheter can be controlled so that thus, the extent of heating in order to evaluate the amount of warming of the target area; can be examined and hence, based on the basis of inter alia this temperature, the power which is to be supplied to this first end can be controlled. Moreover, prior to the actual treatment, with the aid of a relatively reduced small amount of power, the abutment of this said first end against the wall can be examined, assessed based on the basis of the rise in temperature increase which is measured in this said first end. The In fact, is that a peerless good abutment will lead to a smaller temperature rise increase when the power supplied remains the same. Moreover, the temperature in the liquid fluid, in particular blood, is to be prevented from rising too much around the said first end because, as a result thereof, clogging can occur as a result thereof, which clogging can lead to dangerous situations in the body. Moreover, too strong a heating of the first end of the catheter can lead to blistering, explosions due to boiling of entrapped liquid in the wall of the respective cavity such as the heart, which is dangerous to the health and, in extreme cases, can lead to openings in the heart wall, while, furthermore, the danger exists that undesirably large areas are affected, as a result of which damage to, for instance, an atrioventricular AV-node can occur. In order to be able to measure this temperature, it is known to include a temperature sensor such as a thermocouple in the said first end.

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In order to prevent thesaid first end of the catheter from being heated too strongly, it has been proposed to cool this first end. To that end, Wittkampf (Journal of the American College of Cardiology 1988, 11, p.17A) has described a catheter wherein a liquidfluid channel is provided in the catheter, which channel terminates in outlet openings in thesaid first end.

5 A cooling fluidmedium such as physiological saltsaline solution can be urgedforced through thissaid channel and, during use, effects permanentprovides continuous cooling of thesaid first end during use. Thus, the temperature thereof can be kept low. However, a drawbackdisadvantage of this known catheter is that, in it, the actual temperature of thesaid first end cannot be accurately measured.

10 In order to solve this drawbackdisadvantage, it has already been proposed to also include a thermocouple in thesaid first end in such a catheter. However, as a result of thesaid cooling, this is inaccurate. Consequently, the temperature change of thesaid end mentioned and, hence, of for instance the liquidfluid, in particular the blood around thissaid first end or the temperature of the wall, cannot be verified sufficiently accurately, so that clots can still occur, while, moreover, the extent of the temperature riseincrease of the wall cannot be sufficiently controlled and verified. AsBecause the first end of this catheter remains relatively cool, no deposits of such clots will be detected on the outsidesaid exterior, which entails the risk that it can be wrongfully assumed, wrongfully, that during the treatment no clots have formed during the treatment. TheIn fact, is that the liquidfluid, in particular the blood around thissaid first end and/or the wall, may very well have been heated such that coagulation has occurred, having resulting in clots as a result.

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25 In an alternative embodiment, a catheter is provided with a closed channel extending through thesaid first end, while with which the first end is cooled from the inside. Here, the same dangers arise as with the above-described catheter while with which, moreover, the great disadvantagedrawback occurs in that the blood is not cooled at all.

The object of the invention is aims to provide a catheter with which, in a safe and accurate manner, treatments that require local heating of a body cavity wall, such as ablation, can be performed in a safe and accurate manner wherein in a body cavity, local heating of a wall, such as ablation, is to be obtained.

30 A further object of The invention is furthermore aims to provide such a catheter with which, during use, in a simple and accurate manner, abutment of a first end thereof against a wall can be examinedassessed during use in a simple and accurate manner.

A further object of the invention is to provide a catheter of with which, during use, the first, leading end can be heated during use in a simple and accurate manner, in particular with the aid of current, while whereby clots can be prevented in a simple manner.

5 The invention further contemplates aims to provide ing such a catheter which is compatible with existing devices for ablation techniques.

A number of these and other objects is achieved with a catheter according to the invention.

With a catheter according to the invention, an elongated body is provided, through which a livecurrent-carrying wire extends, coupled to an electrically-conductive first end. 10 Moreover, through this elongated body, a channel extends through said elongated body and terminatinges in or near a leading first end into at least one outlet opening. During use, liquidfluid can be guided through thissaid channel, which liquidfluid can flow from thisout of said at least firstone outlet opening. In or near thesaid first end, a temperature sensor has been arranged, with which, during use, the temperature of thissaid first end can be measured during use. 15

With a catheter according to the invention, a thermal separation is provided between thesaid channel and thesaid first end. This thermal separation has been arrangedis provided such that during use, liquidfluid flowing through the channel during use practicallysubstantially does not come into contact with thesaid first end before it flows from theout of said at least one first outflow opening. Thus, during use, it is ensured that it is not the first end that is cooled by the liquidsaid fluid, at least not directly, but that it is rather the liquidfluid extending therearound, in particular blood. With this, coagulation can be prevented while the temperature of thesaid first end can be accurately measured. 20

In an advantageous embodiment, a catheter according to the invention is further characterized in that thissaid channel has a longitudinal direction and is provided with a series of outlet openings, which outlet openings are positioned such that cooling fluidmedium supplied, during use, through thissaid channel flows through thesaid outlet openings in an outflow direction, which includingforms an angle with thesaid longitudinal direction mentioned. This angle is for instance between 30° and 90°, more particularly between 45° and 90°, so that the outflow direction is directed substantially fares away from the outside of the first end. Furthermore, alsoan outlet opening can also be provided in the axially leading end of thesaid first end, an outlet opening can be provided. 25 30

In an alternative embodiment, one or more outlet openings can be provided in a leading longitudinal edge of thesaid body, such that during use, a flow is obtained

substantially along the outside surface of thissaid first end. To that end, the respective at least one outlet opening can be located adjacent thesaid first end, when viewed in front view. An advantage of such an embodiment can be, for instance, a simple construction, no channel extending through the respective first end and/or an advantageous outflow pattern.

5 In an advantageous embodiment, the or each outlet opening is designedimplemented such that a slightlysomewhat turbulent flow is obtainedcreated around thesaid first end, so that coagulation is prevented even better.

10 In a practical embodiment, at least in and/or adjacent the first end, the channel and/or the outlet openings are provided with a thermally-insulating insideinner casing and/or designedare formed in a thermally poorly-conductive material. Herein, thermally poorly-conductive is understood to at least include a heat transfer across the wall of the channel to the first end which is considerably smallerless, for instance 10% or more, more inparticularly 25% or more, smaller than the heat transfer across the wall of a channel which would occur in suchwith a similar catheter withof similar dimensions, but without such thermally-insulating features.

15 The temperature sensor, which can for instance be designedimplemented in a known manner as a thermocouple, is preferably includedincorporated in the first end, at a distance from the interface between thesaid first end and the body of the catheter, preferably adjacent the middle of the electrode. As a result, an accurate temperature measurement of thissaid first end becomes possible. With automatically performed treatments, this sensor can also be used as a switch.

20 The first end can be manufactured from a thermally and electrically conductive material such as metal. Also, only an outer casing can be provided with metal, on, for instance, a plastic, ceramic or glass core, so thatwhereby already a part of the desired thermal insulation can be obtained.

25 The invention further relates to a method for thermal treatment such as ablation, characterized by the features of claim 9.

With such a method, inamoreaccuratemanner, the temperature of a first end of an ablation catheter can be moreaccurately checked and controlled, so that inanaccurateand safemanner, ablations and other thermal treatments can be accuratelyandsafely performed in body cavities such as blood vessels, a heart and the like. With a method according to the invention, the temperature of a wall part of a body cavity can be especiallyaccurately controlled particularlyaccurately, without the danger arising that coagulation occurs in blood flowing around thissaid wall part. Coagulation of proteins in blood can lead to clot formation,

which clots can become dislodged in the blood flow and can lead to, for instance, to infarcts. In particular in the left ventricle and atrium of the heart, clots are to be avoided, in particular, in the left ventricle and atrium of the heart. With a method according to the invention, preferably, the temperature of the blood around this said wall part is preferably kept below the coagulation temperature, while the tip of the employed catheter used and/or the to-be-treated wall part to be treated can be heated to the desired, optionally possibly higher, temperature. The or each electrode is then thereby substantially heated substantially through by the nearby adjacent wall, in which wherein a temperature increase occurs as a result of resistance. The extent of contact between the wall and the electrode will therefore be of influence to the heating of the electrode. This is a reason why a contact measurement can be important.

With this method, preferably in a known manner, a cooling fluid such as a physiological salt saline solution is supplied, preferably in a known manner, through a channel extending through the catheter, which cooling fluid is directly introduced into the respective body cavity. In a method according to the invention, preferably, this said cooling fluid is preferably thermally insulated to a high extent from the material of the leading first end of the catheter leading during use, so that the blood around this first end is cooled more intensively than the first end itself. Preferably, the temperature of the first end is then measured accurately thereby, so that whereby the temperature of the wall, against which or at which the catheter is held, can be accurately controlled.

With the aid of this said cooling fluid, the temperature of the blood around this said first end is preferably kept lower than approximately 55°C. The temperature of the outside of the first end is then thereby preferably kept below approximately 65°C.

With the aid of the cooling fluid, turbulence is preferably generated in the blood around this said first end, so that whereby clot formation in the blood is prevented even better.

In the further subclaims, further advantageous embodiments of the invention are described. In clarification For explanation of the invention, embodiments of the invention will be further described with reference to the drawings. In the drawing Therein:

Fig. 1 schematically shows a catheter according to the invention with a first end in a heart ventricle;

Fig. 2 schematically shows a number of catheters in a heart, for a treatment of heart rhythm disturbances cardiac arrhythmias;

Fig. 3 schematically shows, greatly enlarged, in cross section, a forward end of a catheter according to the invention, in a first embodiment;

Fig. 4 schematically shows, greatly enlarged, in cross section, a forward end of a catheter according to the invention, in a second embodiment;

Fig. 5 schematically shows, greatly enlarged, in cross section, a forward end of a catheter according to the invention, in a third embodiment; and

5 Fig. 5A shows a cross section along the line VA-VA in Fig. 5.

In this description, identical or corresponding parts have identical or corresponding reference numerals. The depicted embodiments shown are only given only by way of example and should not be construed as being limitative in any manner. In particular, combinations of parts of the embodiments shown are also understood to be described herein. Herein, aA body cavity is understood herein to include at least each part of a human or animal body which can 10 be reached by a forward end of a catheter.

In Fig. 1 it is schematically shown how a catheter 1 has been inserted into a heart 2 of a patient 3. A forward end 4 of a catheter 1A is inserted into a ventricle 5, in particular a right ventricle of the heart, while the corresponding forward end 4 of the a second catheter 1B is inserted into the right atrium 6 of the heart 2. This is merely shown as an illustration of possible positions. The catheter(s) has/have or has/have been/is or are inserted into the heart 2 from, for instance, the groin of the patient 3, which is a known method known per se and will therefore not be described further; no more than the known method and device for controlling these catheters and the works/mechanisms thereto in the catheter also will not be described.

20 In Fig. 2, in cross section, a heart 2 is shown in cross section, with left and right ventricle 5A, 5B and left and right atrium 6Aa, 6B. Into this heart 2, Four catheters 1 have been inserted into this heart 2. During, for instance, a measurement and/or treatment of heart rhythm disturbancescardiac arrhythmias, one or more catheters 1 can be inserted into the heart 2, in order to obtain a clear picture of the electric currents in the heart. Each of the depicted 25 catheters 1shown has a body 7 which is elongated and can be guided through the vascular system of the patient. The body 7 has a forward end 4, further to behereinafter called the first end 4, which is inserted as far as into the heart 2. In, or at least adjacent the first end, a number of electrodes 8 isare provided in the form of metal rings, for instance three, which are separated from each other by electrically insulating material of the body and each can be connected, with electronic equipment via a conductive wire through the body 7 to electronic equipment, so that, in a manner known per se, measurements can be carried out in a known manner, for instance an electrogram can be made.

The first end 4 is further provided with a tip 9 manufactured from an electrically conductive material such as metal, which tip, can be connected via an electrically-conductive

wire 10 (Figs. 3-6), can be connected to with said electronic equipment (mentioned but not shown), with which, via the wire 10, current can be fed via the wire 10 into thissaid tip 9. During the measurement and/or the treatment, the patient lies on an electrically conductive underground sub-surface, for instance on a earthed grounding plate (not shown). For performing the treatment, for instance an ablation, the tip 9 of the catheter 1 is pressed against the wall 11 of the heart 2, so that a current will start to runflow through thissaid wall 11. As a result of electrical resistance of the tissue of the wall, heat development will occur adjacent to the tip 9, so that whereby tissue can be treated, in particular heart muscle cells can be killed, so that undesired conduction pathways in the heart 2 or undesired sources of heart rhythm disturbances arrhythmias can be blocked. This is a known treatment, called ablation technique, for preventing heart rhythm disturbances cardiac arrhythmias. For a further description of these techniques, reference is made to the publications and relevant manuals mentioned in the introduction and relevant manuals.

It is known to use a cooling fluid in a catheter 1 for use in, for instance, ablation techniques. This liquid is brought through a channel in the catheter to the forward end of the catheter and from there, it is either introduced into the blood stream or returned through the catheter. At the inside of the catheter, the cooling fluid is then thereby brought against the inside of the catheter into intimate close contact with the to-be-cooled electrode, to be cooled such as the tip of the catheter, in order to cool this electrode and thus thereby prevent deposition of proteins on the outside. Such a catheter is, for instance, described in EP 0 856 292. However, such catheters have the drawback disadvantage that the temperature of the respective electrode, such as the tip, no longer yields offers a good picture representation of the heat development in thissaid wall 11 and/or in the blood B around thissaid electrode.

With a catheter 1 according to the invention, these drawbacks disadvantages have been solved in that, during use, thesaid electrode such as the tip 9, is not cooled, at least not directly, but that rather the blood B is, so that, in the blood, no coagulation occurs and clots are prevented. As a result, the temperature of the respective electrode, such as the tip 9, can be accurately measured and controlled, while, from it, an estimate can be made of the temperature of the wall 11 can be accurately made from it.

Hereinafter, a number of examples of catheters 1 according to the invention is will be described.

In Fig. 3, a first embodiment of a forward end of a catheter 1 according to the invention is shown, in cross-sectional side view.

This catheter 1 comprises an elongated body 7 with a first end 4, formed by a tip 9 made of an electrically and thermally conductive material, in particular metal such as platinum. The body has a longitudinal axis A-A and comprises a substantially cylindrical wall 12 through which a channel 13 extends. Between the wall 12 and the channel 13, there is an annular space 14 through which extends, for instance, the electrically conductive wire 10, the different connecting points for the electrodes 8 and known control means known per se (not shown) for controlling of the end 4. Moreover, ~~through the annular space 14~~ a second electrically-conductive wire 15 extends through the annular space 14, which wire 15 is connected to a thermocouple 16.

In the embodiment shown in Fig. 3, the tip 9 is coupled to the body 7 by means of a coupling part 18 which is attached, for instance glued, byto a first side ~~within~~inside the wall 12, and, on the other side, is fitted in a compatible second snap edge 20 of the tip 9 via a snap edge 19. In this embodiment, the thermocouple 16 ~~has been~~is arranged in or against the interface 17 between the body 7 and the tip 9, at least on the end surface 21 of the tip 9 proximal to the body 7 and the coupling part 18.

In the first end 4, in particular in the tip 9, a channel part 22 is provided extending in line with the axis A-A and is connected to the channel 13, for instance in that because a sleeve 23 extends from thesaid end surface 21 in the channel 13 and is fitted therein. From an outsideexterior 41 of the tip 9, first bores 24 are provided reaching as far as into the channel part 22 and extending substantially radially. These first bores 24 all have a longitudinal axis 25 including forming an angle α with the longitudinal axis A-A of the body 7, for instance approximately 90° . A second bore 26 is provided in line with the channel 13, at least with the axis A-A, which bore 26 terminates in the apex 36 of the tip 9. In each bore 24, 26, as well as around the channel part 22, a thermally insulating casing 27 is provided, such, that during use a cooling fluid, in particular a physiological saltsaline solution, can be passed through the channel 13, the channel part 22 and the bores 24, 26 without direct contact occurring between the cooling fluid and (the inside of) the tip 9. Thus, direct cooling of the tip 9 by the cooling fluid is thereby prevented for thein larger part. In the elaborationembodiment of Fig. 3, the sleeve 23 is not thermally insulated.

In Fig. 4, a first, more advantageous alternative embodiment of a first end 4 of a catheter 1 according to the invention is shown, distinguished from the one according to Fig. 3 in that herein, also—the sleeve 13 is also thermally insulated, while, moreover, the thermocouple 16 is also arranged closer to the apex 36 of the tip 9, so thatwhereby an even more accurate temperature measurement of, in particular, the heart wall can be performed.

In Fig. 5, a further alternative embodiment is shown, with only tip 9 in cross-sectional side view, which, as to built up, largely corresponds in a constructional sense to the one of the elaborationsembodiments of Figs. 3 and 4. However, here, a tip 9 is provided herein that has having a core 28, which is manufactured from a material with having a low thermal and/or electrical conductivity, for instance glass, ceramics or plastic, and a casing 29 with, relative thereto, having a good heat conductivity and/or electrical conductivity relative thereto. Herein, only in the casing 29 the bores 24, 26 have been provided with a thermal inside inner casing only in the casing 29, at least formed as part of the core 28, so that in a simple manner whereby the desired thermal insulation is obtained in a simple manner. In this embodiment, the longitudinal axes 25 extend approximately tangentially relative to the channel part 22 (Fig. 5A) and include form an angle α with the longitudinal axis A-A₁ which angle deviates from 90°, for instance approximately 75° to 80°, such that the outflow direction is slightly somewhat in the direction of the apex 36, at least in the direction of the wall 11. Thus Thereby, the cooling of the blood around the tip 9 and adjacent the wall 11 can be even more improved even more. A thermocouple 16 has been provided against is attached to the casing 29.

In the embodiments according to the Figs. 3-5, each time, the extremity end of each bore 24, 26 always forms an outflow opening 30 for cooling fluid. These outflow openings 30 can for instance be formed such that during use a turbulent flow is generated in the blood flowing by. Means that can be used to that end therefor are known from hydrofluid dynamics. In the embodiments shown, For instance, thirteen outflow openings have been are provided in the depicted embodiments, but it will be clear that any desired number of outflow openings 30 can be provided.

Optionally, one or more outlet openings can be provided near the electrode, in particular near the interface 17 between the body 7 and the tip 9, one or more outlet openings can be provided, so that a part of the cooling fluid is directed along the tip 9, at least along the outer surface of the electrode, for direct cooling of the blood and/or for generating turbulence.

When using a catheter 1 according to the invention in a treatment of, for instance, heart rhythm disturbances cardiac arrhythmias or the like, wherein an ablation technique is used in a body cavity, in which flown through with blood is flowing through, such as a ventricle or atrium of a heart or an artery or a vein, preferably, the current intensity and the supply of cooling fluid is are preferably regulated such, that the temperature of the blood around the tip 9 is kept below the coagulation temperature. In practice, this means below approximately 55°C, so that no coagulation occurs. Preferably, the temperature of the tip 9 is

regulated such that it does not exceed 65°C. In practice, this has appeared to be a reasonably safe limit. With larger electrodes (of a length of, for instance, 8 mm instead of 4 mm), the flowing blood will provide relatively proportionally more cooling will occur to blood flowing around so that there is a larger difference between the tissue and electrode temperature.

5 With an 8 mm tip, 50 to 55° is a good target value, at least with existing electrodes. The electrode will clearly remain cooler than the heated tissue of the wall, which is kept below 100°C in order to prevent the earlier-mentioned explosions. In Fig. 3, schematically, in the wall 11 an area 40 is schematically indicated in the wall 11 wherein which heat development occurs as a result of the current passed through the wall 11, as described earlier.

10 Naturally, as to dimension and shape, this area of influenced area 40 depends on the current intensity used, and the duration of the treatment and is only given by way of as an indication.

The invention is not limited in any manner to the exemplary embodiments given in the description and the drawing. Many variations thereon are possible within the framework of the invention as outlined by the claims.

15 For instance, different materials can be used for the different parts, and outflow openings can be provided in different manners, as long as, at least substantially, the tip 9 is at least substantially prevented from being cooled from the inside by cooling fluid flowing therethrough. The leading end of the catheter can have any desired shape and can also be used enat different locations than in the heart, for instance also for fighting tumors and such aberrations or for providing targeted creation of scar tissue in a controlled manner. A catheter according to the invention can also be provided with several electrodes, at least one of which being provided with a cooling device according to the invention, with insulated outflow openings. Also, only one electrode can be provided at a distance offrom the end.

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These and many comparable variations are understood to fall within the framework of
25 the invention as outlined by the claims.

CLAIMS

1. A catheter, provided with an elongated body with having an electrically conductive first end, wherein through said body at least one live current-carrying wire extends through said body, which wire is connected to said first end, and a channel for feeding supplying a cooling fluid through said body extends through said body, which channel is provided, in or near said first end, with at least one outlet opening in or near said first end and wherein, in said first end, a temperature sensor has beenis arranged in said first end, while wherein said channel is thermally insulated from said first end.

10 2. A catheter according to claim 1, wherein said at least one outflow opening is provided in said first end.

3. A catheter according to claim 1 or 2, wherein said channel has a longitudinal direction and is provided with a series of outlet openings is provided, which outlet openings are arranged such that, during use, cooling fluid supplied through said channel flows out through said outlet openings in an outflow direction which includesforms an angle with said longitudinal direction.

15 4. A catheter according to claim 1 or 2, wherein the outlet openings are provided with a thermally insulating inside inner casing.

5. A catheter according to any one of the preceding claims, wherein at least one said outlet opening is provided in said body, adjacent said first end.

20 6. A catheter according to any one of the preceding claims, wherein said first end is attached to said body, wherein said temperature sensor is provided in said first end, at a distance from an interface formed between said body and said first end.

7. A catheter according to any one of the preceding claims, wherein the outlet openings are designedformed such that cooling fluid flowing therefrom during use flows away from said first end.

25 8. A catheter according to any one of the preceding claims, wherein said first end has at least one metal outside exterior.

9. A method for thermal treatment, in particular ablation, wherein a catheter with having an electrically conductive first end is providedarranged in a body cavity, with said first end near or, preferably, against a wall of said body cavity, while wherein at a distance from said first end a complementary electrically conductive element is arranged at a distance from said first end, preferably outside the body in which said cavity is located, whereupon an electric current is generated between said first end and said conductive element, such that said wall is

heated, whereupon in, adjacent said first end, a cooling fluid is dispensed adjacent said first end, while wherein the temperature of said first end is measured and is regulated, while wherein direct cooling of said first end from the inside thereof by said cooling fluid is prevented.

5 10. A method according to claim 9, wherein said cooling fluid, through a channel in said catheter, is supplied through a channel in said catheter and is dispensed in said protein-containing liquid fluid, while wherein said cooling fluid in said catheter is separated by thermal insulation from at least said first end through thermal insulation.

10 11. A method according to claim 9 or 10, wherein the cooling fluid is dispensed in a protein-containing liquid fluid such as blood around said first end such that said protein-containing liquid fluid is cooled with the aid of said cooling fluid adjacent an interface between said protein-containing liquid fluid and said wall and near the outside exterior of said first end and is kept at a temperature below the coagulation temperature of said protein-containing liquid fluid.

15 12. A method according to any one of claims 9-11, wherein said ablation is performed in a body cavity wherein as liquid, within which blood is present as fluid, while wherein the temperature of said blood is kept at a temperature below approximately 55°C and the temperature of said first end is regulated such that it remains below approximately 65°C.

20 13. A method according to any one of claim 9-12, wherein as cooling fluid a physiological salt saline solution is used as the cooling fluid, which is introduced into said protein-containing liquid fluid such that around said first end, turbulence occurs in said protein-containing liquid fluid around said first end.